K092566

OCT - 9 2009

Nanosphere

Summary of 510(k)

510(k) numbers:	K092566: Verigene® Respiratory Virus Nucleic Acid Test on the Verigene® *SP* System ($RVNAT_{SP}$)
Summary preparation date:	October 7, 2009
Submitted by:	Nanosphere, Inc. 4088 Commercial Avenue Northbrook, IL 60062 Phone: 847-400-9000 Fax: 847-400-9199
Contact:	Gregory W. Shipp, M.D. Chief Medical Officer VP, Medical and Regulatory Affairs and Quality Assurance
Proprietary names:	*For instrument:* Verigene® SP System *For the assay:* Verigene® Respiratory Virus Nucleic Acid Test on the Verigene® *SP* System ($RVNAT_{SP}$)
Common names:	*For the instrument:* Bench-top molecular diagnostics workstation *For the assays:* Respiratory panel Respiratory virus panel Respiratory viruses Influenza A assay Influenza B assay RSV assay Influenza A/B and RSV assay
Comparison VRNAT and $RVNAT_{SP}$:	Additional claim to the 510(k) application, **K083088** is described. The Verigene Respiratory Virus Nucleic Acid Test (**VRNAT**) will add the **Verigene *SP* System** to the labeling as a cleared system. The safety and effectiveness of the Verigene® Respiratory Virus Nucleic Acid Test on the Verigene *SP* System (**$RVNAT_{SP}$**) is demonstrated with analytical and method comparison studies. The FDA-cleared **VRNAT** (K083088) is a qualitative test based on identifying virus-specific nucleic acids for Influenza A virus, Influenza B virus, and respiratory syncytial virus (RSV). Within this test, the steps of sample preparation (or nucleic acid extraction), target amplification, and hybridization test and analysis take place on three separate instruments (Table 1). The **$RVNAT_{SP}$** is the same assay with additional system claims for the Verigene *SP* System, a modified Verigene® System that allows sample preparation, target amplification, and hybridization test and analysis using a single system (Table 1).

Table 1.

	Sample Preparation	Target Amplification	Hybridization Test and Analysis
VRNAT (cleared, K083088)	NucliSENS EasyMAG (bioMerieux)	Thermocycler	Verigene System
$RVNAT_{SP}$	Verigene *SP* System	Verigene *SP* System	Verigene *SP* System

Device description:

The $RVNAT_{SP}$ is designed to identify virus-specific nucleic acids for Influenza A virus, Influenza B virus, and respiratory syncytial virus (RSV). The $RVNAT_{SP}$ involves:

1) Sample Preparation – magnetic bead-based viral RNA extraction from nasopharyngeal swab specimens obtained from symptomatic patients;
2) Target Amplification – Multiplex RT-PCR-based amplification of the eluted viral RNA targets to generate virus-specific amplicons;
3) Verigene Hybridization Test and Analysis – detection and identification of virus-specific amplicons by using gold nanoparticle probe-based technology.

The entire $RVNAT_{SP}$ is performed on the Verigene® *SP* System, which is a bench-top molecular diagnostics workstation that consists of two instruments, the **Verigene *SP* Processor** and the **Verigene Reader**. The Verigene *SP* Processor performs the assay steps on each sample by using a robotic pipettor to transfer and mix reagents within and between separate testing modules designed for nucleic acid extraction, target amplification, and the Verigene Hybridization test. The Verigene hybridization test module is the same as in the previous Verigene System with added modules for nucleic acid extraction and RT-PCR target amplification. Key functions of the Verigene *SP* Processor include:

1) Reading of the barcode identification label on inserted Test Consumables to maintain positive identification of patient samples throughout processing.
2) Facilitation of nucleic acid extraction, multiplex RT-PCR target amplification, and the Verigene Hybridization Test.
3) Real-time communication of test processing status to the Reader.

The Verigene Reader is the same instrument as in the FDA-cleared VRNAT. It is a free-standing instrument with a touch screen control panel and a wand-based barcode scanner. It utilizes a graphical user interface to guide the user through the process of ordering tests and reporting results. There are no serviceable parts and no user calibration is required. Interaction with the touch screen is minimized through barcode use. This instrument also serves as the reader of the Test Cartridges using advanced optics. The key functions of the Verigene Reader include:

1) Entry and tracking of specimen identification numbers via manual keyboard input or via barcode-reader wand.
2) Test selection for each specimen.
3) Automated transfer of specimen processing instructions on Test Cartridge-specific basis to linked Processor unit(s). A single Reader unit can control up to 32 Processor units.
4) Automated imaging and analysis of Test Cartridges.
5) Results display.
6) Results report generation.

$RVNAT_{SP}$ consumables within each single-use disposable test kit include: (i) Tip Holder Assembly; (ii) Extraction Tray; (iii) Amplification Tray; and (iv) RV Test Cartridge. The kit components are inserted into the corresponding module of the Verigene *SP* Processor prior to each test, and the sample is added to the Extraction Tray. Patient information is entered into the Reader to initiate the test procedure.

1) Tip Holder Assembly – The robotic pipettor picks up pipettes from the Tip Holder Assembly. The pipettes are used for mixing and transferring reagents within the test procedure.

	2) Extraction Tray – Nucleic acids are extracted from the sample by using magnetic bead-based methods within the Extraction Tray. Each Tray contains reagents for a single extraction procedure. A robotic pipette transfers reagents to designated wells within the Extraction Tray to affect the steps of lysis, capture of nucleic acids onto the magnetic beads, washing, and eluting the isolated nucleic acids from the magnetic beads. 3) Amplification Tray – The isolated nucleic acids are amplified by using multiplex RT-PCR within the Amplification Tray. Each Tray contains reagents for a single multiplex RT-PCR procedure. A robotic pipette transfers the reagents to a specific well within the Amplification Tray. A set thermal profile is then initiated to perform all of the amplification related steps including UDG-based decontamination, reverse transcription, and multiplex PCR in a single tube. Upon completion, an aliquot of the amplified sample is mixed with hybridization buffer containing the virus specific mediator probes. The sample is then transferred to the Test Cartridge. 4) RV Test Cartridge for Verigene Hybridization Test – The virus-specific amplicons are detected and identified within a Test Cartridge by using specific nucleic acid probes in conjunction with gold nanoparticle probe-based detection technology. Each Test Cartridge is a self-contained, laboratory consumable that consists of two parts. The upper housing of each cartridge is called the "reagent pack" and contains reservoirs filled with the detection reagents. When in place with the 'substrate holder', the reagent pack creates an air-tight hybridization chamber surrounding the region of the substrate containing a target-specific capture array. As each step of the test is completed, old reagents are moved out of the hybridization chamber and new reagents are added from the reagent pack via microfluidic channels and pumps. Once the test is complete, the Test Cartridge is removed from the Verigene *SP* Processor unit and the reagent pack is snapped off and discarded. The remaining slide is now ready for imaging and analysis in the Verigene Reader. 5) End-point detection on the Verigene Reader: The test slide is inserted into the Verigene Reader wherein it is illuminated along its side. The gold-silver aggregates at the test sites scatter the light, which is in turn captured by a photosensor. The relative intensity arising from each arrayed test site is tabulated. Net signals, defined as the absolute signal intensities with background signals subtracted, are compared with thresholds determined by negative controls within the slide in order to arrive at a decision regarding the presence or absence of target. These results are linked to the test and patient information entered at the beginning of each test session to provide a comprehensive results file.
Intended uses:	The RVNAT$_{SP}$ is a qualitative multiplex *in vitro* diagnostic test for the detection and identification of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids purified from nasopharyngeal swab specimens obtained from patients symptomatic for viral upper respiratory infection. The test is intended to be used on the Verigene® *SP* System as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV infections. The test is not intended to detect Influenza C virus. Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other management decisions. It is recommended that negative test results be confirmed by culture. Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infections with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Predicate device:	The cleared Verigene® Respiratory Virus Nucleic Acid Test (VRNAT), K083088 is claimed as the predicate device (**Table 2**). It is a multiplex *in vitro* diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV).

Table 2. Similarities and Differences between the Cleared and the New System.

Feature	VRNAT (Predicate, K083088)	Verigene RVNAT$_{SP}$
Intended use	The **Verigene® Respiratory Virus Nucleic Acid Test on Verigene *SP* System (RVNAT$_{SP}$)** is a qualitative multiplex *in vitro* diagnostic test for the detection and identification of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids purified from nasopharyngeal swab specimens obtained from patients symptomatic for viral upper respiratory infection. The test is intended to be used on the Verigene® *SP* System as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV infections. The test is not intended to detect Influenza C virus. Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other management decisions. It is recommended that negative results be confirmed by culture. Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	Same test on Verigene *SP* System
Targets	Influenza A, Influenza B, RSV	Identical
Specimen	Nasopharyngeal swabs in sample matrix	Identical
Sample preparation	Automated extraction of nucleic acids performed externally on the NucliSENS EasyMAG (bioMerieux) using silica coated magnetic beads and chaotropic salts using chemistry based on U.S. Patent 5,234,809.	Automated extraction of nucleic acids performed on the Verigene *SP* Processor using silica coated magnetic beads and chaotropic salts licensing the identical patent chemistry.
Sample size	200 µL	Identical
Quality control	Internal procedural quality control, external quality control solutions	Identical
Amplification method	Multiplex RT-PCR: Target Amplification by RT-PCR is performed on an external thermocycler	Multiplex RT-PCR: Identical reagents; performed within the added Amplification Module on the Verigene *SP* Processor
	M-MLV Reverse Transcriptase	Identical

Pipetting	Pipetting between the three steps is performed by the user.	Robotic pipettor added to automate fluid transfer steps.
Detection Method	Verigene Hybridization Test is performed in the hybridization module housed in the Processor of the Verigene® System by using single-use Test Cartridges	Identical
Decision algorithm	Target-specific signal intensities are compared to a signal threshold and ratioed against positive and negative controls for a decision.	Identical
Results	Positive or negative qualitative results	Identical
Reader	Provides the user interface, controls the Processor, performs image analysis, and provides results.	Identical
Software	A custom embedded software application running under the Micro-C/OS real-time operating system.	Architecture is the same. Additional software programming to control the Extraction and Amplification Modules.
Reagent storage	Test Cartridge: 2 - 8 °C Amplification Kit: -20 °C	Test Cartridge and Extraction Tray: 2 - 8 °C. Amplification Tray: -20 °C
Assay Performance	As in the cleared VRNAT (K083088).	Identical Limits of Detection as the cleared VRNAT. Precision/Reproducibility – Clinically and statistically equivalent. Method Comparison – Clinically and statistically equivalent

Performance Characteristics of the RVNAT$_{SP}$

Analytical and method comparison studies to establish the performance of the test on the Verigene *SP* System are described.

A. Comparison of Analytical Sensitivity

The analytical sensitivity of the RVNAT$_{SP}$ was compared to the cleared VRNAT (K083088) by determining the Limit of Detection (LOD) of Influenza A, Influenza B, RSV A, and RSV B viruses. Strains with established titers were used for each virus. Each virus stock was serially diluted into a sample matrix (Universal Transport Media, Copan), and each concentration was tested in quadruplicate using the RVNAT$_{SP}$. The LOD was confirmed by performing an additional 20 replicates for each strain in order to demonstrate that the virus was detected ≥95% of the time. The LOD for each virus was identical to the LOD observed with the same strains on the cleared VRNAT (K083088) (Table 3).

Table 3. Limit of Detection

Limits of Detection	Concentration
Influenza A (A/Wisconsin/67/05)	2 TCID50/mL
Influenza B (B/Florida/04/2006)	50 TCID50/mL
RSV A (Strain Long)	10 TCID50/mL
RSV B (B-1 Wild Type (B WV/14617/85))	2 TCID50/mL

B. Carryover and Crossover Contamination Studies

High positive samples of Influenza A, Influenza B, RSV A, and RSV B were alternated with high negative samples for all four viruses. Based on the collective data, there was no evidence of cross-contamination from any of the test steps including sample extraction, multiplex RT-PCR step, and the Verigene Hybridization Test.

C. Precision/Reproducibility Studies Comparison between the RVNAT$_{SP}$ and the cleared VRNAT (K083088)

The Precision/Reproducibility Studies were performed at each of three sites. At Site 1, the Reproducibility Study was part of a larger precision study. Precision/Reproducibility Studies for the RVNAT$_{SP}$ were conducted *exactly* as for the previously cleared VRNAT (K083088) to allow equivalency comparisons. As before, eight unique samples were created by diluting known concentrations of viral particles with Viral Transport Medium (**Table 4**). Since the Analytical Sensitivity of the RVNAT$_{SP}$ was identical to the cleared VRNAT, the same strains and levels were used in the studies. Each strain was represented at 3 distinct concentrations: high negative, low positive, and moderate positive.

Table 4. Sample panel for the Precision/Reproducibility Studies.

Unique Samples	Viral Strains and Levels
1	Influenza A - High Negative; Influenza B - High Negative
2	RSV A - High Negative; RSV B – High Negative
3	Influenza A - Low Positive
4	Influenza B - Low Positive
5	RSV A - Low Positive
6	RSV B - Low Positive
7	Influenza A - Moderate Positive; RSV A - Moderate Positive
8	Influenza B - Moderate Positive; RSV B - Moderate Positive

The Precision Study (Site 1) tested the sample set over 12 non-consecutive days. On each test day, two operators performed the RVNAT$_{SP}$ in duplicate for each sample (i.e., 4 sample sets per day total). In the reproducibility study performed by sites 2 and 3, the sample set was tested in triplicate daily by 2 operators on each of five non-consecutive days.

Performance characteristics of the RVNAT$_{SP}$ in the Precision/Reproducibility Studies were equivalent to those for the cleared VRNAT (Table 5).

Table 5. Comparison of Precision/Reproducibility data from the new RVNAT$_{SP}$ to the cleared VRNAT

		Agreement of 'Observed Results' to 'Expected Results'											
		New RVNAT$_{SP}$						Cleared VRNAT					
Panel Member		Site 1	Site 2	Site 3	All Sites	% Agreement	95% Score CI	Site 1	Site 2	Site 3	All Sites	% Agreement	95% Score CI
Influenza A	High Negative	48/48	15/15	15/15	78/78	100%	95.3 - 100%	46/48	14/15	15/15	75/78	96%	89.3 - 98.7%
	Low Positive	48/48	15/15	15/15	78/78	100%	95.3 - 100%	48/48	14/15	15/15	77/78	98.7%	93.1 - 99.8%
	Moderate Positive	48/48	15/15	15/15	78/78	100%	95.3 - 100%	48/48	15/15	15/15	78/78	100.0%	95.3 - 100%
Influenza B	High Negative	48/48	15/15	15/15	78/78	100%	95.3 - 100%	48/48	15/15	15/15	78/78	100%	95.3 - 100%
	Low Positive	47/48	15/15	15/15	77/78	98.7%	93.1 - 99.8%	47/48	15/15	15/15	77/78	98.7%	93.1 - 99.8%
	Moderate Positive	48/48	15/15	15/15	78/78	100%	95.3 - 100%	48/48	15/15	15/15	78/78	100%	95.3 - 100%
RSV A	High Negative	48/48	15/15	14/15	77/78	99%	93.1 - 99.8%	48/48	13/15	15/15	76/78	97%	91.1 - 99.3%
	Low Positive	47/48	15/15	15/15	77/78	98.7%	93.1 - 99.8%	47/48	15/15	15/15	77/78	98.7%	93.1 - 99.8%
	Moderate Positive	48/48	15/15	15/15	78/78	100.0%	95.3 - 100%	48/48	15/15	15/15	78/78	100.0%	95.3 - 100%
RSV B	High Negative	48/48	15/15	15/15	78/78	100%	95.3 - 100%	46/48	14/15	14/15	74/78	95%	87.5 - 98.0%
	Low Positive	48/48	15/15	15/15	78/78	100%	95.3 - 100%	48/48	15/15	15/15	78/78	100%	95.3 - 100%
	Moderate Positive	48/48	15/15	15/15	78/78	100%	95.3 - 100%	48/48	15/15	15/15	78/78	100.0%	95.3 - 100%

D. Method Comparison Studies for $RVNAT_{SP}$ and the cleared VRNAT (K083088)

A sample set representing Influenza A, Influenza B, and RSV was prepared by diluting culture positive nasopharyngeal swab samples with negative samples (Table 6). Dilutions were aimed to yield viral load levels close to the low positive levels for each virus type. A total of 62 unique samples were diluted, aliquoted, and frozen. The sample set was tested at the internal site (Site 1) using the cleared VRNAT, and at all three sites using the $RVNAT_{SP}$ for a total of 62x4=248 unique tests.

Each sample set yielded a total of 186 decisions from 62 unique samples as each test provides a decision of 'Detected' or 'Not Detected' for each of the 3 viruses, Influenza A, Influenza B, and RSV. Of the 62 samples, 3 samples had dual infections where 2 viruses were present.

Table 6. Method Comparison Study Sample Set.

Sample Set	Positives	Negatives	Totals
Influenza A	15	47	62
Influenza B	16	46	62
RSV A/B	34	28	62
Total	**65***	**121**	**186**

*3 samples had 2 viruses raising the total number of positives from 62 to 65

Decisions on the $RVNAT_{SP}$ for each site were compared to the cleared VRNAT. The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) are provided in Tables 7 – 10. The two systems are equivalent based on the collected data.

Table 7. $RVNAT_{SP}$ Method Comparison Data collected at Site 1

All Viruses		VRNAT (Old System)			
		Positive	**Negative**	**Total**	
$RVNAT_{SP}$ (New System)	**Positive**	**65**	**0**	**65**	PPA 100.0 % (95%CI=94.4% - 100.0%)
	Negative	**0**	**121**	**121**	NPA 100.0% (95%CI=96.9% - 100.0%)
	Total	**65**	**121**	**186**	

Table 8. $RVNAT_{SP}$ Method Comparison Data collected at Site 2

All Viruses		VRNAT (Old System)			
		Positive	**Negative**	**Total**	
$RVNAT_{SP}$ (New System)	**Positive**	**64**	**0**	**64**	PPA 98.5 % (95%CI=91.8% - 99.7%)
	Negative	**1[a]**	**121**	**122**	NPA 100.0% (95%CI=96.9% - 100.0%)
	Total	**65**	**121**	**186**	

[a]Low positive discordant Influenza A. Repeat tests were positive and gave the expected result.

Table 9. RVNAT$_{SP}$ Method Comparison Data collected at Site 3

All Viruses		VRNAT (Old System)			
		Positive	Negative	Total	
RVNAT$_{SP}$ (New System)	Positive	62	0	62	PPA 95.4 % (95%CI=87.3% - 98.4%)
	Negative	3[a]	121	124	NPA 100.0% (95%CI=96.9% - 100.0%)
	Total	65	121	186	

[a]All discordant samples were Influenza A low positive Repeat tests were positive and gave the expected result.

Table 10. RVNAT$_{SP}$ Method Comparison Data – Combined data from all 3 sites

All Viruses/All Sites		VRNAT (Old System)			
		Positive	Negative	Total	
RVNAT$_{SP}$ (New System)	Positive	191	0	191	PPA 97.9 % (95%CI=94.8% - 99.0%)
	Negative	4[a]	363	367	NPA 100.0% (95%CI=99.0% - 100.0%)
	Total	195	363	558	

[a]All discordant samples were Influenza A low positive. Repeat tests were positive and gave the expected result.

Conclusions Concerning Claim of Substantial Equivalence

The FDA-cleared VRNAT (K083088) is a multiplexed, qualitative test, based on identifying virus-specific nucleic acids for Influenza A virus, Influenza B virus, and Respiratory Syncytial Virus (RSV). Nucleic acids are externally extracted and amplified from viruses and then detected within the Verigene® System by using single-use disposable Test Cartridges.

The RVNAT$_{SP}$ is the identical test as the cleared VRNAT with regard to sample extraction chemistry, RT-PCR amplification reagents, and assay detection methods, but it is performed on the Verigene *SP* System, a fully automated 'sample-to-result' device. As with the Verigene System, the Verigene *SP* System comprises two units: Reader and *SP* Processor. The *SP* Processor has the same hybridization module as the Verigene Processor plus additional modules for sample extraction and multiplex RT-PCR – steps that are performed externally on two separate instruments in the cleared VRNAT.

Assay comparison studies were performed for the RVNAT$_{SP}$. The studies included:

1) Analytical Sensitivity (Limits of Detection) determination of the RVNAT$_{SP}$
   - The analytical sensitivities or Limits of Detection (LOD) of RVNAT$_{SP}$ were identical to the cleared VRNAT for the Influenza A, Influenza B, RSV A, and RSV B strains tested, demonstrating that the performance characteristics of the two devices were equivalent.
2) Carryover and Cross-contamination Studies on the RVNAT$_{SP}$
   - The carryover and cross-contamination studies showed no evidence of contamination in the RVNAT$_{SP}$.
3) Precision/Reproducibility studies on the RVNAT$_{SP}$ and comparison to the corresponding VRNAT studies
   - The Precision/Reproducibility studies performed across three clinical test sites replicated the study that was performed previously for the cleared VRNAT. Comparison of the clinical outcomes and the statistical results for the Precision/Reproducibility studies showed equivalence between the RVNAT$_{SP}$ and the cleared VRNAT.

4) Method Comparison Studies on the $RVNAT_{SP}$ (New) and VRNAT (Cleared).

   - In a comparison study conducted across three sites, the same set of samples was compared between the $RVNAT_{SP}$ and the cleared VRNAT. The collective lower bound 95% CI for the positive and negative percent agreements was greater than 90%. Moreover, comparisons of signal intensities between the two devices showed equivalent performance across sites and across the individual tests. Collectively, the data showed that the $RVNAT_{SP}$ and the cleared VRNAT performance were equivalent.

The performance data support the claims of equivalence between the $RVNAT_{SP}$ and the cleared VRNAT. Thus, the performance characteristics in the package insert for the cleared VRNAT with respect to accuracy, sensitivity, specificity, and additional attributes are applicable to the $RVNAT_{SP}$.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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OCT - 9 2009

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Re: K092566
Trade/Device Name: Verigene® Respiratory Virus Nucleic Acid Test on the Verigene® SP System
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OCC, NSU
Dated: September 29, 2009
Received: September 30, 2009

Dear Dr. Shipp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092566

Device Name: Verigene® Respiratory Virus Nucleic Acid Test on the Verigene® *SP* System ($RVNAT_{SP}$)

Indication for Use:

The Verigene® Respiratory Virus Nucleic Acid Test on the Verigene *SP* System ($RVNAT_{SP}$) is a qualitative multiplex *in vitro* diagnostic test for the detection and identification of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids purified from nasopharyngeal swab specimens obtained from patients symptomatic for viral upper respiratory infection. The test is intended to be used on the Verigene® *SP* System as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV infections. The test is not intended to detect Influenza C virus.

Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other management decisions. It is recommended that negative test results be confirmed by culture.

Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

Uwe Scherf
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K092566